REMARKS/ARGUMENTS

Section 112, First Paragraph Arguments

Applicants respectfully disagree with the Examiner's contention that there is insufficient support under section 112, first paragraph for Claims 1-9. The Examiner states that the claims have "been amended to recite limitations that are not supported by the specification as originally filed." (Office Action p. 3) The Examiner contends that there is no support for ginger below 50mg; for turmeric below 50 mg; yucca below 400mg and Devil's Claw below 200mg. This is incorrect. The specification expressly provides support for certain combinations of components with no particular weight requirement for each individual component. For example, the specification states:

> In one embodiment, a suitable herbal phytochemical for use in a composition of the present invention includes, but is not limited to cayenne, ginger, turmeric, yucca, Devil's Claw, nettle leaf, Black Cohosh, alfalfa and celery seeds.
>
> Some herbal phytochemicals in the composition have similar or identical functions but the mechanisms employed to achieve the functions may differ. This overlap of functions is advantageous in that individuals often respond differently to a single chemical. Also, the response of an individual may vary based on his environmental and physiological conditions at the time of therapy. Hence, a multiplicity of phytochemicals with similar functions accommodates diversity within and among individuals and populations. It is likely that this multiple component approach is one reason this invention demonstrates faster and greater levels of efficacy than prior art inventions.
> (Specification, pp. 12-13).

Applicants further point out to the Examiner that compositions of mixtures of various components are set forth in the specification without enumerating the "preferred" weight ranges. As such, it is enough that the claimed compositions merely have an amount of each component present (at least up to the amounts as set forth in the claims). For example, the specification expressly supports embodiments where there are no requisite "weight range" limitations, as follows:

Another embodiment of the present invention includes a composition for treating joint disorders in vertebrates. The composition includes:

(a) a palatability agent which can include yeast, yeast autolysates, and/or organ and muscle preparations derived from chicken or bovine;

(b) an herbal phytochemical which can include cayenne, ginger, turmeric, yucca, Devil's Claw, nettle leaf, Black Cohosh, alfalfa and/or celery seeds; and

(c) a metabolic precursor which can include glucosamine, glucosamine salts, chondroitin sulfate, mucopolysaccharides and/or tissue preparations containing chondroitin sulfate. The daily dose of such a composition includes from about 50 to about 2000 mg of the metabolic precursor per 25 pounds of body weight, and from about 2 to about 3000 mg of the phytochemical per 25 pounds of body weight. (Specification, p. 19).

Yet another embodiment of the present invention relates to a method for treating joint disorders in vertebrates. Such a method includes the step of administering to a vertebrate a therapeutically effective quantity of a palatability agent, an herbal phytochemical and a metabolic precursor. The composition preferably includes effective quantities of cayenne, ginger, turmeric, yucca, Devil's Claw, nettle leaf, Black Cohosh, alfalfa, celery seeds, glucosamine and salts thereof, and chondroitin sulfate. Such a composition is effective to increase blood circulation in a vertebrate. In a further embodiment, the composition used in such a method has an effect which can include arresting an inflammatory response, diminishing the oxidative effect of free radicals, suppressing an autoimmune response and/or providing metabolic precursors for biosynthesis of macromolecules necessary in the repair and maintenance of damaged joint tissues. (Specification, pp. 19-20).

According to the present invention, an effective quantity of a component of a composition of the present invention to administer to a vertebrate comprises an amount that is capable of alleviating a joint disorder, without being toxic to the vertebrate. (Specification, p. 21).

Moreover, the ranges provided for in the specification merely relate what the "preferred" ranges are. There was never any intent nor express disclaimer of subject matter that did not fall precisely within such preferred ranges. The expressed ranges for the respective ginger, turmeric, yucca and Devil's Claw components is clearly limited to "preferred" doses, as demonstrated in the specification itself. See, i.e.:

> According to the present invention, when the herbal phytochemical included in a composition for treating joint disorders is ginger or ginger root, the

daily dose for vertebrates is **preferably** from about 50 mg to about 220 mg of ginger or ginger root per 25 pounds of body weight. (Specification, p. 15).

According to the present invention, when the herbal phytochemical included in a composition for treating joint disorders is turmeric, the daily dose for vertebrates is **preferably** from about 50 mg to about 400 mg of turmeric per 25 pounds of body weight. (Specification, p. 15).

According to the present invention, when the herbal phytochemical included in a composition for treating joint disorders is yucca, the daily dose for vertebrates is **preferably** from about 400 mg to about 3000 mg of yucca per 25 pounds of body weight. (Specification, p. 15).

According to the present invention, when the herbal phytochemical included in a composition for treating joint disorders is Devil's Claw, the daily dose for vertebrates is **preferably** from about 200 mg to about 2000 mg of Devil's Claw per 25 pounds of body weight. (Specification, p. 16).

Finally, in contravention of the Examiner's position, it is respectfully noted that one of the Examples supports component weights below the preferred ranges as otherwise set forth in the specification. For example:

Example 3

This example shows the ingredients in a composition for treating joint disorders of the present invention. For each active ingredient listed below, the amount given is equivalent to about a <u>one month supply</u> effective to treat a 50 pound dog. The ingredients are blended in a ratio of 60% active ingredients to 40% palatability enhancer. The palatability enhancer consists of hydrogenated vegetable oils and beef extract.

Active ingredients: cayenne pepper (0.28 g); turmeric (8.4 g); ginger root (5.6 g); Black Cohosh (2.8 g); Yucca root (56 g); Devil's Claw (28 g); nettle leaf (16.8 g); alfalfa leaf (28 g); celery seed (2.8 g); D-glucosamine HCL (28 g) and mucopolysaccharides (78.4 g). (Specification p. 25).

If the one month supply of the composition described above is administered daily to the dog (which was the administration in, for instance, Example 2), then the amount of turmeric in such daily dose would be about 28mg – which is below the 50mg preferred range as set forth elsewhere in the specification. Thus, the specification not only includes support for novel

combinations of ingredients without specific weight ranges specified, the specification further provides evidence that the "preferred" dosages are not to be deemed as a limitation of the scope of the present invention.

As the Federal Circuit noted in *Union Oil v. Atl. Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000) "neither the Patent Act nor the case law of this court requires such detailed disclosure. *See In re Hayes Microcomputer Prods., Inc.*, 982 F.2d 1527, 1533, 25 USPQ2d 1241, 1245 ("[The applicant] does not have to describe exactly the subject matter claimed."); *Vas-Cath*, 935 F.2d at 1566 ("ranges found in applicant's claims need not correspond exactly to those disclosed in [the specification"). Rather, the Patent Act and the case law require only sufficient description to show one of skill in the art that the inventor possessed the claimed invention at the time of filing. The inquiry for adequate written description simply does not depend on a particular claim format, but rather on whether the patent's description would show those of ordinary skill in the art that the inventors possessed the claimed invention at the time of filing.

Here, the specification unmistakably informs those of skill in the art to increase or decrease the various components and to mix various components together to achieve a stated purpose and result.

As the Federal Circuit's predecessor explained in distinguishing *In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967) in another case involving ranges:

> If lack of literal support alone were enough to support a rejection under § 112, then the statement of *In re Lukach* . . . that "the invention claimed does not have to be described *in ipsis verbis* in order to satisfy the description requirement of § 112," is empty verbiage. *In re Wertheim*, 541 F.2d 257, 265 (CCPA 1976). The written description requirement does not require identical descriptions of claimed compounds - it only requires enough disclosure in the patent to show one of skill in this art that the inventor "invented what is claimed." *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

Applicants therefore respectfully request the reconsideration and removal of the §112, first paragraph rejection of claims.

Rejection of Claims 1-6 Under Section 103

The Examiner rejects Claims 1-6 under §103 as being unpatentable over Hirschhorn, Hobbs, Henderson, Manoussos et al. and Castleman references. The Examiner contends that "the references show that all of the claimed elements were known to be used for the same purpose; therefore, it is not considered hindsight to combine the references." The Examiner's argument, however, is not supported by applicable law.

As the Federal Circuit court recently reiterated in *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.* 04-1493 (Fed. Cir. June 9, 2005) and as outlined in *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 (Fed. Cir. 2004), in making the assessment of differences between the prior art and the claimed subject matter, section 103 specifically requires consideration of the claimed invention "as a whole." Inventions typically are new combinations of existing principles or features. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698 (Fed. Cir. 1983) (noting that "virtually all [inventions] are combinations of old elements"). The "as a whole" instruction in title 35 prevents evaluation of the invention part by part. *Ruiz*, 357 F.3d at 1275. Without this important requirement, an obviousness assessment might successfully break an invention into its component parts, then find a prior art reference corresponding to each component. *Id.* This line of reasoning would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. Further, this improper method would discount the value of combining various existing features or principles in a new way to achieve a new result - often the essence of invention. *Id.* Contrary to this reasoning, section 103 requires assessment of the invention as a whole. Id. This "as a whole" assessment of the invention requires a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the various elements from the prior art and combined them in the claimed manner. *Id.* In other words, section 103 requires some suggestion or motivation, before the invention itself, to make the new combination. *See In re Rouffet*, 149 F.3d 1350, 1355-56 (Fed. Cir. 1998).

Simply identifying all of the elements in a claim in the prior art does not render a claim obvious. Ruiz, 357 F.3d at 1275. *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540,

1546, 221 USPQ 1, 7 (Fed. Cir. 1984) ("a combination may be patentable whether it be composed of elements all new, partly new, or all old"); *Fromson v. Advanced Offset Plate, Inc.*, 755 F.2d 1549, 1556 n.3, 225 USPQ 26, 31 n.3 (Fed. Cir. 1985) ("Only God works from nothing. Men must work with old elements.").

Applicants respectfully submit that none of the references relied upon by the Examiner can support an obviousness rejection of the amended claims. (This is especially so given the closed end construction provided in the new claims). Henderson is specifically directed to a catalyst to convert glucosamine into hyaluronic acid and does not teach or suggest any of the other elements in the claimed invention, nor does it provide a motivation to make such a combination. Hirschhorn is solely directed to a report where Devil's Claw was used to treat patients. Hobbs teaches a particular combination of specific elements, many of such elements absent from the present claimed composition, including: liquorice root, chamomile flower, St. John's wort flower, kava kava root, barberry root and camille oil. Hobbs fails to teach or suggest which of the numerous elements in his formulation are critical and which ones can be eliminated. Moreover, Hobbs can be viewed as a teaching away of the present invention in that he advises strict avoidance of red meat consumption when taking the composition. Because the primary focus of the present invention is for use with domestic pets whose diet may principally consist of red meat, Hobbs teaches away rather than towards the present invention.

Manoussos et al. is directed to the use of mucopolysaccharides with respect to cosmetic acid pharmaceutical compositions (col. 1, lines 13-15). The Examiner has failed to point out how this reference can possibly be combined with any of the other references to provide a *prima facie* case of obviousness of the present claims.

Castleman's book entitled "*The Healing Herbs*" separately teaches that alfalfa, black cohosh, ginger and turmeric may each be used in the treatment of arthritis. The Examiner admits that the references to individual components is separated by at least 40 pages, and often by over 300 pages, in Castleman's book. Castleman simply is incapable of being combined with any of the other cited references in a manner to properly present a *prima facie* case of obviousness of the claimed invention.

Applicants direct the Examiner's attention to the fact that the Henderson, Manoussos et al., Hobbs, Hirschhorn and Castleman references were all previously considered prior to issuing the claims in Applicants' prior issued patent, e.g., U.S. Patent No. 6,709,682. In view of the explanation and traversal of the Examiner's §112, first paragraph rejection of claims, it is respectfully submitted that the specification contains support for the claimed amounts of each particular component of the claimed combination of components, and in view of the prior '682 claims being found patentable over the exact same references now being relied upon by the Examiner, the Examiner's present arguments must fail.

Applicants have also previously supplied, in the prosecution of related patents, objective evidence of non-obviousness. Such objective evidence, combined with the lack of a teaching or suggestion to combine the cited references in the way the Examiner has done, supports a conclusion that the present claims are not obvious.

There is simply no teaching or suggestion in any of such references to make the combination made by Applicants other than the guidance provided by the Applicants' disclosure. It is impermissible within the framework of §103 to pick and choose from multiple references only so much as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. *See Polaroid Corporation v. Eastman Kodak Company*, 229 USPQ 561 (Fed. Cir.), cert. denied, 471 US 850 (1996). It is entirely appropriate that combination claims can consist of combinations of old elements. *Clearstream Wastewater Systems v. Hydroaction, Inc.*, 206 F.3d 1440, 1446, 54 USPQ 2d 1185, 1189-1190 (Fed. Cir. 2000). "The notion that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, Section 103." *Panduit Corporation v. Dennison Manufacturing Co.*, 810 F.2d 1561, 1575, 1 USPQ 2d 1593, 1603 (Fed. Cir. 1987). The showing of combinability must be "clear and particular." *In re Dembiczak*, 175 F.3d at 999, 50 USPQ 2d at 1617. The genius of invention is often a combination of known elements which in hindsight seems preordained. When the art in question is relatively simple, the opportunity to judge by hindsight is particularly tempting. Consequently, tests of whether to

combine references need to be applied rigorously. *McGinley v. Franklin Sports, Inc.*, 60 USPQ 2d 1001 (Fed. Cir. 2001). The relevant portions of a reference include not only those teachings which would suggest particular aspects of an invention to one of ordinary skill in the art, but also those teachings which would lead such a person away from the claimed invention. *In re Mercier*, 185 USPQ 774, 778 (CCPA 1975).

Rejection of Claims 7-9 Under 35 U.S.C. §103

The Examiner rejects Claims 7-9 as being unpatentable over a combination of Hobbs, Castleman, Manoussos et al. and Henderson. Applicants incorporate by reference the above-stated arguments and applicable law and respectfully requests that the Examiner reconsider and withdraw all such rejections of claims. Applicants note that all of these references were previously considered in the allowance of similar claims in Applicants' prior '682 patent. The Examiner has failed to present a *prima facie* case of obviousness to combine the references in a manner to arrive at the particular claimed compositions and the Examiner's argument that such combination "flows logically from their having been used individually in the prior art" is simply unsupportable in view of the above Federal Circuit precedent. Applicants, to avoid redundancy, incorporate by reference the previous arguments with respect to "obvious to try" theories and Applicants repeat that the Examiner's contention that one of ordinary skill in the art would have made such particular combination simply because each of the substances individually "would also be useful in creating an arthritis-treating composition" is tantamount to such an "obvious to try" theory. Such theory has been rejected by the Federal Circuit as being an inappropriate §103 argument. Indeed, Applicants note that even the Examiner has admitted that "the references do not specifically teach adding the ingredients in the amounts claimed by Applicant." More importantly, however, Applicants respectfully submit that none of the references teach the particular combination of elements, regardless of their respective dosage amounts. Thus, it is not correct to view the present invention as a mere optimization of parameters because none of the prior art teaches the particular combination itself.

Based upon the above-referenced well established law, it is not at all clear that the combination made by the Examiner would have been made by one of ordinary skill in the art, and is even less clear whether the requisite motivation exists to make such combination. *See In re Lee*, the Federal Circuit court expressed skepticism about invoking the knowledge of a skilled artisan to supply the motivation to combine on a scanty record. 277 F.3d 1338, 1343-44 (Fed. Cir. 2002) ("This factual question of motivation . . . could not be resolved on subjective belief and unknown authority."). That individual arthritic treatments utilizing various different components is sufficient to provide such motivation is not at all "clear and particular". Applicants respectfully request that the Examiner reconsider and withdraw all such rejection of claims.

Finally, the demonstration of unexpected results apparently desired by the Examiner has been provided in prior prosecution of related patents and is supplemented by the present Declaration of Ms. Rebecca Rose. The secondary considerations of non-obviousness in this case are particularly convincing and compelling. These clearly overcome any obviousness concerns that the Examiner may otherwise have.

Added Claims

The added claims present claims using a partially closed ended transitional phase "consisting essentially of", which Applicants believe further distances the claimed invention from the prior art. Applicants request the favorable consideration and passage to allowance of such claims.

Applicants' counsel request the courtesy of a telephone interview to expedite the passage to allowance of the present claims and can be reached directly at (303) 863-2977.

7/7/05
Date

Respectfully submitted,

SHERIDAN ROSS P.C.

By: _____
Joseph E. Kovarik
Registration No. 33,005
1560 Broadway, Suite 1200
Denver, Colorado 80202-5141
(303) 863-9700

J:\4018\-1\-con\-2\amendment and response after final.wpd